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In Guilty Plea, OxyContin Maker to Pay \$600 Million

By BARRY MEIER MAY 10, 2007

ABINGDON, Va., May 10 — The company that makes the narcotic painkiller OxyContin and three current and former executives pleaded guilty today in federal court here to criminal charges that they misled regulators, doctors and patients about the drug's risk of addiction and its potential to be abused.

To resolve criminal and civil charges related to the drug's "misbranding," the parent of Purdue Pharma, the company that markets OxyContin, agreed to pay some \$600 million in fines and other payments, one of the largest amounts ever paid by a drug company in such a case.

Also, in a rare move, three executives of Purdue Pharma, including its president and its top lawyer, pleaded guilty today as individuals to misbranding, a criminal violation. They agreed to pay a total of \$34.5 million in fines.

OxyContin is a powerful, long-acting narcotic that provides relief of serious pain for up to 12 hours. Initially, Purdue Pharma contended that OxyContin, because of its time-release formulation, posed a lower threat of abuse and addiction to patients than do traditional, shorter-acting painkillers like Percocet or Vicodin.

That claim became the linchpin of the most aggressive marketing campaign ever undertaken by a pharmaceutical company for a narcotic painkiller. Just a few years after the drug's introduction in 1996, annual sales reached \$1 billion. Purdue Pharma heavily promoted OxyContin to doctors like general practitioners, who had

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often had little training in the treatment of serious pain or in recognizing signs of drug abuse in patients.

But both experienced drug abusers and novices, including teenagers, soon discovered that chewing an OxyContin tablet or crushing one and then snorting the powder or injecting it with a needle produced a high as powerful as heroin. By 2000, parts of the United States, particularly rural areas, began to see skyrocketing rates of addiction and crime related to use of the drug.

More details about the plea agreements were expected to be announced at a news conference this afternoon in Roanoke, Va., by John L. Brownlee, the United States attorney for the Western District of Virginia. “Misbranding” is a broad statute that makes it a crime to mislabel a drug, fraudulently promote it or market it for an unapproved use.

In a proceeding this morning in United States District Court here, both Purdue Pharma and the three executives acknowledged that the company fraudulently marketed OxyContin for six years as a drug that was less prone to abuse, as well as one that also had fewer narcotic side effects.

In a statement, the company said: “Nearly six years and longer ago, some employees made, or told other employees to make, certain statements about OxyContin to some health care professionals that were inconsistent with the F.D.A.-approved prescribing information for OxyContin and the express warnings it contained about risks associated with the medicine. The statements also violated written company policies requiring adherence to the prescribing information.”

“We accept responsibility for those past misstatements and regret that they were made,” the statement said.

The time period covered by the guilty pleas runs from late 1995, when the Food and Drug Administration approved OxyContin for sale, to mid-2001, when Purdue Pharma, faced with both public criticism and regulatory scrutiny, dropped its initial marketing claims for the drug.

Federal officials said that internal Purdue Pharma documents show that company officials recognized even before the drug was marketed that they would face stiff resistance from doctors who were concerned about the potential of a high-powered narcotic like OxyContin to be abused by patients or cause addiction.

As a result, company officials developed a fraudulent marketing campaign designed to promote OxyContin as a time-released drug that was less prone to such problems. The crucial ingredient in OxyContin is oxycodone, a narcotic that has been used for many years. But unlike other medications like Percocet that contain oxycodone along with other ingredients, OxyContin is pure oxycodone, with a large amount in each tablet because of the time-release design.

The drug has proven to be valuable in treating serious, long-lasting pain.

Purdue Pharma acknowledged in the court proceeding today that “with the intent to defraud or mislead,” it marketed and promoted OxyContin as a drug that was less addictive, less subject to abuse and less likely to cause other narcotic side effects than other pain medications.

For instance, when the painkiller was first approved, F.D.A. officials allowed Purdue Pharma to state that the time-release of a narcotic like OxyContin “is believed to reduce” its potential to be abused.

But according to federal officials, Purdue sales representatives falsely told doctors that the statement, rather than simply being a theory, meant that OxyContin had a lower potential for addiction or abuse than drugs like Percocet. Among other things, company sales officials were allowed to draw their own fake scientific charts, which they then distributed to doctors, to support that misleading abuse-related claim, federal officials said.

Between 1995 and 2001, OxyContin brought in \$2.8 billion in revenue for Purdue Pharma, a closely held company based in Stamford, Conn. At one point, the drug accounted for 90 percent of the company’s sales.

As part of the plea agreement, Purdue Frederick, a holding company for Purdue Pharma that is also closely held, pleaded guilty to a felony charge of misbranding

OxyContin. Of the \$600 million the company agreed to pay in criminal and civil penalties, some \$470 million represents fines to federal and state agencies. The remaining \$130 million represents payments to settle civil litigation brought by patients and other private plaintiffs.

Purdue Pharma has also agreed, among other things, to subject itself to independent monitoring of its practices. The three top former and current Purdue Pharma executives pleaded guilty to criminal misdemeanor charges of misbranding, a charge that does not require prosecutors to show knowledge or intent on the executives' part. However, the three individuals ran Purdue Pharma during the period in question.

Those executives are: Michael Friedman, the company's president, who agreed to pay \$19 million in fines; Howard R. Udell, its top lawyer, who agreed to pay \$8 million; and Dr. Paul D. Goldenheim, its former medical director, who agreed to pay \$7.5 million.

In a separate statement, Purdue said: "Mr. Friedman, Dr. Goldenheim (while at Purdue) and Mr. Udell neither engaged in nor tolerated the misconduct at issue in this investigation. To the contrary, they took steps to prevent any misstatements in the marketing or promotion of OxyContin and to correct any such misstatements of which they became aware."